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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,534

06/01/2006

Christopher John Burns

415852000200

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25225 7590 10/12/2010  
MORRISON & FOERSTER LLP  
12531 HIGH BLUFF DRIVE  
SUITE 100  
SAN DIEGO, CA 92130-2040

EXAMINER

WILLIS, DOUGLAS M

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

10/12/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/581,534	BURNS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	DOUGLAS M. WILLIS	1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 August 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-12 and 14-30 is/are pending in the application.
- 4a) Of the above claim(s) 15-20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12, 22, 29 and 30 is/are allowed.
- 6) ☒ Claim(s) 10, 14, 23 and 26 is/are rejected.
- 7) ☒ Claim(s) 11, 21, 24, 25, 27 and 28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

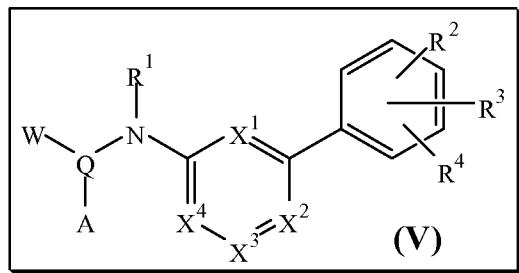
### *Status of the Claims / Priority*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the *Final Rejection*, mailed on May 25, 2010, has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on August 25, 2010, has been entered.

Claims 10-12 and 14-30 are pending in the current application. According to the *Claim Amendments*, filed August 25, 2010, claims 1-9 and 13 were cancelled. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/AU2004/001689, filed December 3, 2004, which claims priority under 35 U.S.C. § 119(a-d) to AU 2003906680, filed December 3, 2003.

### *Status of Restrictions / Election of Species*

Applicant's affirmation of the following election, without traverse, in the reply filed on



April 15, 2010, is acknowledged: a) Group II - claims 10-12, 14 and 21-30, where  $X_1 = -N-$ ;  $X_2 = -N-$ ;  $X_3 = -C-$ ; and  $X_4 = -C-$ ; and b) substituted pyrimidine of formula (V) - p. 48, example 18.

The requirement was made FINAL in the *Non-Final Rejection*, mailed on February 2, 2010.

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Claims 15-20 were withdrawn from further consideration, pursuant to 37 CFR 1.142(b), as being drawn to a nonelected or cancelled invention, there being no allowable generic or linking claim.

The sections of U.S.C. Title 35 that formed the basis of prior rejections formulated, as well as any references supporting said rejections, that are not included with this Office action, may be found in either the *Non-Final Rejection*, mailed on February 2, 2010, or the *Final Rejection*, mailed on May 25, 2010. Furthermore, any rejections and/or objections of record not explicitly addressed herein below, are hereby withdrawn, in light of applicant's arguments and/or the *Claim Amendments*, filed August 25, 2010.

Thus, a third Office action and prosecution on the merits of claims 10-12, 14 and 21-30 is contained within.

### ***Claim Objections***

Claim 10 is objected to because of the following informalities:  $R^{22}, R^{23}$  should be replaced with  $R^{22}$  **and**  $R^{23}$ . Appropriate correction is required.

Claims 11, 24 and 25 are independently objected to because of the following informalities: the claims are dependent upon a rejected base claim. Appropriate correction is required.

Claims 21, 27 and 28 are independently objected to because of the following informalities: the claims are dependent upon an objected base claim. Appropriate correction is required.

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***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

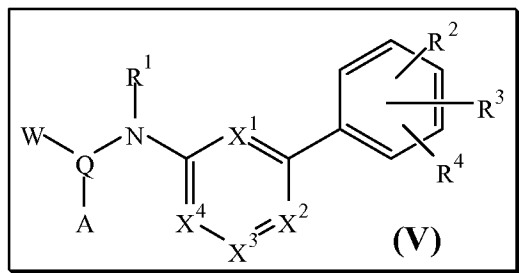
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10, 14, 23 and 26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yonetoku, et al. in WO 03/026661.

The instant application recites substituted pyrimidines and compositions of the formula

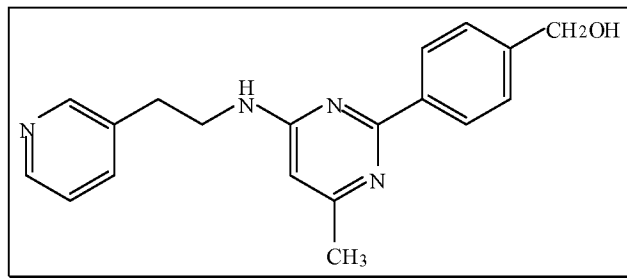


(V), shown to the left, where  $X^1 = -N-$ ;  $X^2 = -N-$ ;  $X^3 = -CY-$ , wherein  $Y = -C_{1-4}alkyl$ ;  $X^4 = -CY-$ , wherein  $Y = -H$ ;  $Q = -C_{1-4}alkyl-$ ; **W** =  **$-C_{1-4}alkyl$** ; **A** =  **$-hetaryl$** ;  $R^1 = -H$ ;  $R^2 = -C_{1-6}alkylOH$ ;  $R^3 = -H$ ; and  $R^4 = -H$ , as

tubulin inhibitors.

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Yonetoku, et al. (WO 03/026661), as provided in the file and cited in the IDS, teaches substituted pyrimidines of the formula (V), shown to the right, where  $X^1 = -N-$ ;  $X^2 = -N-$ ;  $X^3 = -CY-$ , wherein  $Y = -CH_3$ ;  $X^4 = -CY-$ , wherein  $Y = -H$ ;  $Q = -CH_2CH_2-$ ;  $W = -H$ ;  $A =$  -pyrid-3-yl;  $R^1 = -H$ ;  $R^2 = -CH_2OH$ ;  $R^3 = -H$ ; and  $R^4 = -H$ , as insulin secretion accelerators [p. 59, Table 12, example 349].



The only difference between the instantly recited substituted pyrimidines of the formula (V) and Yonetoku's substituted pyrimidines is  $W$  is  $-CH_3$  in the instantly recited substituted pyrimidines of the formula (V), whereas  $W$  is  $-H$  in Yonetoku's substituted pyrimidines.

In the chemical arts, it is widely accepted that *structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions or compounds, creates a prima facie case of obviousness.* {See *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, No. 06-1329, slip op. at 9 (Fed. Cir. June 28, 2007) (quoting *In re Dillon*, 919 F.2d 688, 692 [16 USPQ2d 1897] (Fed. Cir. 1990) (en banc)); and *In re Papesch*, 315 F.2d 381 [137 USPQ 43] (C.C.P.A. 1963)}.

Similarly, it is well established that *the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results.* {See *In re Lincoln*, 126 USPQ 477, 53 USPQ 40 (CCPA 1942); *In re Druey*, 319 F.2d 237, 138 USPQ 39 (CCPA 1963); *In re Lohr*, 317 F.2d 388, 137 USPQ 548 (CCPA 1963); *In re Hoehsema*, 399 F.2d 269, 158 USPQ 598 (CCPA 1968); *In re Wood*, 582 F.2d 638, 199 USPQ 137 (CCPA

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1978); *In re Hoke*, 560 F.2d 436, 195 USPQ 148 (CCPA 1977); *Ex parte Fauque*, 121 USPQ 425 (POBA 1954); and *Ex parte Henkel*, 130 USPQ 474 (POBA 1960)}.

Moreover, it is also well established that *it is obvious to add a carrier or solvent to an unpatentable compound*. {See *Ex parte Douros and Vanderweff*, 163 USPQ 667, (BPAI 1968)}.

Consequently, since: a) Yonetoku teaches substituted pyrimidines, where *W* is -H; b) the courts have recognized that *structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions or compounds, creates a prima facie case of obviousness*; c) the courts have further recognized that *the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results*; and d) the courts have further recognized that *it is obvious to add a carrier or solvent to an unpatentable compound*, one having ordinary skill in the art, at the time this invention was made, would have been motivated to utilize the teachings of Yonetoku and (a) replace the -H at *W* in Yonetoku's substituted pyrimidines, with an alternatively usable -CH<sub>3</sub>, and (b) formulate a composition thereof, with a reasonable expectation of success and similar therapeutic activity, rendering claims 10, 14, 23 and 26 obvious.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

***Allowable Subject Matter***

Claims 12, 22, 29 and 30 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

The limitation on the core of the substituted pyrimidines of the formula (V) that is not taught or fairly suggested in the prior art is  $R^2$  on the periphery of the pyrimidine core. This limitation is present in all of the recited species in claims 12 and 29, respectively.

Consequently, the species recited in claims 12 and 29, respectively, are neither anticipated, nor reasonably obviated, by the prior art.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOUGLAS M. WILLIS, whose telephone number is 571-270-5757. The examiner can normally be reached on Monday thru Thursday from 8:00-6:00 EST. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/DOUGLAS M WILLIS/  
Examiner, Art Unit 1624**

**/James O. Wilson/  
Supervisory Patent Examiner, AU 1624/**